EXHIBITS 1-2 FILED UNDER SEAL

EXHIBIT 3

Yee Article Excerpt

(Full 108-page Article available at http://www.wcrinet.org/studies/public/books/wcri_why_surgeon_owners_do_more_surgery.pdf)



WHY SURGEON OWNERS OF AMBULATORY SURGICAL CENTERS Do More Surgery Than Non-Owners

Christine A. Yee

WC-12-17

May 2012

WORKERS COMPENSATION RESEARCH INSTITUTE CAMBRIDGE, MASSACHUSETTS

Applying the Findings on Financial Incentives of Ownership

The findings show that surgeon owners performed more surgeries in Florida (1997–2004) as a result of the financial incentives from (co-)owning an ASC. The reader should keep the following in mind when generalizing the findings to other states, to more recent years, and to the impact on overall medical costs and utilization.

When generalizing to other states or even Florida today, the reader should recognize that the larger the profits from surgeries, the larger the impact of these financial incentives will be on medical costs and utilization. During the period of the study, reimbursement rates in Florida for workers' compensation surgeries were relatively low compared with today and with other states. Estimates of the impact may be higher in states with higher reimbursement rates or even in Florida today. Further, if a state's workers' compensation reimbursement rates were relatively higher than that of other payors when compared with Florida during 1997 to 2004, we might expect the financial interest effect in that state to be larger than what we found in this study.

When using the findings to estimate the total impact of ASCs and of physician ownership on medical costs, it is important to recognize that the estimates presented here do not represent a complete picture of this impact. If ASCs yield better patient outcomes, such as a reduction in secondary surgeries or readmissions, system costs may be lowered. On the other hand, financial incentives could lead to additional ancillary costs, even if there were no increase in surgery. For example, carpal tunnel release may be done as either an open or closed procedure. Both are common. The ancillary costs, however, differ. If the financial incentives from ownership lead surgeon owners to use more often the approach that generated the highest revenue for an ASC, one would need to include the ancillary costs in the total cost of ownership. This study did not attempt to measure whether this was material or not.

When generalizing from the study period to today, the reader should remember that the number of surgery centers has grown substantially, at least through 2008–2009. In Florida, the number of ASCs that performed KSWC surgeries grew 5.9 percent annually during our study period. In the United States (2004–2009), the number of Medicare-certified ASCs grew 5.1 percent annually (MedPAC, 2011). Since owners are incentivized and able to do more surgery than non-owners, and most ASCs have physician owners, the growth in the number of ASCs alone would lead to more KSWC surgeries performed, which may contribute to medical costs. However, this study does not address whether patient outcomes improved from these additional surgeries or not.

EXHIBIT 4

The Enduring Temptation of Physician Self-Referral | Managed Care Magazine Online



MANAGED CARE October 2011. © MediMedia USA

The Enduring Temptation of Physician Self-Referral

Lax regulations and fee-for-service payment make an irresistible mix for physician conflicts. Are ACOs the answer?

Richard Mark Kirkner

Share Tweet 0 Share 0 8+1 0

Almost 50 years ago economist Kenneth Arrow warned about agent moral hazard — the temptation for physicians to exploit their knowledge edge over patients for economic gain. Today, physicians are bombarded with potential conflicts of interests between their obligations to patients and their desire to maximize their incomes. Tepid federal regulations have largely left health plans on their own in trying to police these conflicts.

Physician conflicts of interest take two notable forms: where physicians own part of the facility, usually an imaging center or ambulatory surgery center (ASC), that they're referring patients to — the principle of self-referral, and where drug companies and medical device manufacturers pay physicians fees or provide other incentives to use their products. Because the rules, regulations, and guidelines for these two practices are so different, this article will focus on self-referral. Those who have documented self-referral trends are holding out hope that a shift away from fee-for-service payment may yet curb these temptations, but they also say health plans would be better served by tougher regulations.

License to overuse?

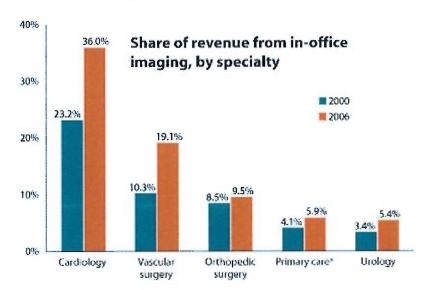
Several studies have documented that doctors who have a stake in a referring facility have higher utilization rates than other colleagues. Health plans have tried to curtail this urge with radiology benefit management companies for imaging and appropriate-use criteria for other procedures, largely in the absence of meaningful regulations, according to

8/6/2015

people who have studied physician self-referral.

"This is a huge problem," says Jean Mitchell, PhD, a Georgetown Public Policy Institute economist who has studied self-referral. The Medicare Payment Advisory Commission (MedPAC) has estimated that 1 in 3 imaging studies may be unnecessary. That would equal about \$55 billion of the \$170 billion spent on imaging annually, according to Jeff Goldsmith, PhD, president of Health Futures, coauthor of a book about medical imaging, and a member of MANAGED CARE'S Editorial Advisory Board.

A 2008 white paper from America's Health Insurance Plans (AHIP) estimated that up to 50 percent of high-tech imaging may be unnecessary. MedPAC's June report to Congress concludes that "physician investments in diagnostic testing equipment have contributed to rapid growth of these services under the physician fee schedule and resulted in levels of utilization that are likely to include unnecessary services." Meanwhile, MedPAC has found that the share of revenue from in-office imaging has almost doubled for vascular surgery and increased 50 percent for cardiology between 2000 and 2006.



Source: Medicare Payment Advisory Committee

The temptations are almost identical with ASCs. A 2010 study showed that not only did self-referring physicians in Florida order more procedures than non-stakeholders, but they typically stepped up referrals after they acquired an interest. Physicians also frequently self-refer to specialty surgery hospitals and clinical laboratories, but imaging centers and ASCs have drawn the most scrutiny. Specialty surgery hospitals are the only self-referral entity the Affordable Care Act (ACA) bans outright, but centers that existed before this year are grandfathered in.

Two federal statutes regulate self-referral under Medicare and Medicaid: section 1877 of

The Enduring Temptation of Physician Self-Referral | Managed Care Magazine Online

the Social Security Act, commonly called "Stark II" for its author, Rep. Pete Stark of California, and the so-called antikickback statute. Stark II is a civil statute and applies to designated health services, whereas the antikickback law is a criminal statute and applies to all referrals. Some states have their own laws. Maryland, for example, has a strict 1993 ban on physician self-referral that just this year a state appeals court upheld.

Both federal laws have their loopholes. In Stark II, it's the in-office ancillary services exception that allows physicians to self-refer for "in-office" services. However, as Mitchell explains, the law has been distorted beyond recognition. "The definition of 'the office' has expanded dramatically," she says. "It might be the imaging center that you have a lease agreement with, or it might be a satellite lab that you claim is part of your office. That's a big problem."

The loophole in the antikickback law exists in the safe harbors provision. This allows physicians to invest in a facility as long as they perform at least 30 percent of their annual cases there, according to John Hollingsworth, MD, a University of Michigan urologist and health economist who has studied self-referral. The Department of Health and Human Services Office of Inspector General has issued countless safe harbor regulations over the years.

The ACA requires physicians to disclose their investment in a facility and give patients a list of alternative locations, but otherwise does little to curb self-referral.

"The only real restriction on self-referral in the Affordable Care Act was the decision not to permit the expansion of physician-owned hospitals," Goldsmith says. "But from an imaging standpoint, the really expensive one is the in-office ancillary services exception, which was left untouched." Adds Mitchell: "The Affordable Care Act has done nothing."

Imaging centers

Mitchell published a study in Health Affairs in 2007 that showed physicians were exploiting loopholes in Stark II to continue self-referring to imaging centers. Her study found that 33 percent of providers in California who referred for MRI and 22 percent for CT scans classified them as self-referral. However, as she found out, that did not necessarily mean they owned the equipment; instead, about two thirds were involved in lease or "pay per click" arrangements that, she says, might violate federal and state laws.

She describes two common leasing arrangements. One involves a provider group leasing time on a hospital's equipment, for example an MRI. "Say I'm with an orthopedic surgery group. I go to a hospital and say, You either sell us time on Mondays on your MRI machine for \$5,000 a day or we're going to open our own and put you out of business."

The Enduring Temptation of Physician Self-Referral | Managed Care Magazine Online

These provider groups get favorable terms from hospitals or radiology groups. "The bottom line is they're really sticking it to them," she says. "Pay per click" is a scheme where the referring physician pays the imaging center a flat fee for each scan. "The physician has an arrangement to pay the center \$300 per scan, but then turns around and bills Medicare or a private payer \$1,200 and pockets the difference," Mitchell says.

Goldsmith and Bruce Hillman, MD, have criticized health plans that use radiology benefit managers (RBMs) to pre-authorize imaging studies. Their Health Affairs study, published last year, drew on previous studies that showed physicians use high-tech imaging more when they benefit financially from self-referral. "Our top-level conclusion was that it was a lot more efficient to simply prohibit certain forms of self-referral than to impose case-by-case review," Goldsmith says. Their book, The Sorcerer's Apprentice: How Medical Imaging Is Reshaping Health Care, further questions the use of RBMs.

They also explored why physicians have turned to imaging to supplement their incomes. "The health care system has been unwilling to pay physicians sufficiently for the cognitive work that they do," Goldsmith says. "We've created far too much reward for capital intensive investment and the use of that capital in diagnosing patients."

AHIP, meanwhile, claims that RBM programs have borne fruit. According to a 2008 AHIP white paper, member plans reported up to an 82 percent drop in inappropriate imaging studies. Older programs using RBMs reduced the average growth of utilization from 25 percent to 1 percent, according to AHIP.

Besides cost, payers have another incentive for reining in unnecessary imaging. The National Council on Radiation Protection and Measurement, the agency that establishes standards for radiation exposure, has reported that medical radiation exposure of the U.S. population has increased more than seven-fold since 1980. The 2008 AHIP white paper stated that 1.5 percent to 2 percent of all U.S. cancers may be caused by radiation exposure.

ASCs and self-referral

By sheer numbers, ambulatory surgery centers are a force to behold: Last year about 5,200 centers performed more than 5 million procedures, according to the Ambulatory Surgery Center Association. Since 2000, their numbers have grown by about 50 percent, according to Hollingsworth. Physicians hold a stake in about 83 percent of these facilities and own 43 percent of them outright.

In a 2010 Health Affairs article, Hollingsworth drew a strong correlation between physician ownership in ASCs and higher utilization. His study specifically looked at physician referral

8/6/2015

and utilization rates for five common outpatient procedures at ASCs in Florida over three years. "What we found for a variety of procedures is that after acquisition of ownership status, the proceduralist's use of surgery increased more rapidly than ... counterparts who didn't acquire ownership status," Hollingsworth says.

Another study found that at physician-owned facilities, physicians are more likely to refer privately insured patients to their own facilities while sending Medicaid patients to hospital outpatient departments (HOPDs). The lead investigator, Jon Gabel, PhD, senior fellow at National Opinion Research, says this trend should give insurers pause.

"If I'm a commercial insurer, I would say it's probably good news because my guess is it costs less to treat those same patients at an ASC rather than the hospital," he says. "On the other hand I would want to be assured we have good utilization management because if profitability leads to higher use of services, then the commercial insurers had better review those patients treated more carefully."

As David Shapiro, MD, chairman of the Ambulatory Surgery Centers Association (ASCA), sees it, any association between ASC ownership and higher utilization is purely statistical. "I have not seen or read anything that makes the case that ownership causes anything except good patient care and prudent use of health care resources," he says. In fact, Shapiro points to "considerable savings" that those ASCs have passed on to health plans. According to a 2009 ASCA study, Medicare's payments to ASCs were 86.5 percent of HOPD payments in 2003, and subsequent policy changes have increased the difference.

Hollingsworth acknowledges the purely statistical nature of utilization trends.

Nonetheless, policymakers want to know what's driving this behavior. "Some of it could be attributable to changes in providers' referrals after the acquisition of ownership. If they're getting more referrals, their volume could be increasing for reasons unrelated to ownership," Hollingsworth says. "Some of it could be related to productivity: Ownership kind of entitles a surgeon or a proceduralist to more control over the practice environment." Other reasons he points to are that ASCs are simply more efficient than hospitals and a provider may have the case volume to justify investment in the ASC.

"There's a financial outlay that goes along with ownership, and if you don't have that caseload, then it's probably not worth it to invest in something like that," Hollingsworth says. "Then the other obvious thing on the table is the extent to which you are more likely to use something you own."

How to rein in self-referral

Public policy types have put forward several ideas for tempering the temptations of self-

8/6/2015

referral, from strengthening federal law to scrapping the fee-for-service system. Hollingsworth points to accountable care organizations as one potential solution. "I wouldn't say it's a disincentive, but a surgery center would be viewed as a cost center here because you'd be doing more surgery and taking money away from the population," he says.

MedPAC prefers a move toward ACOs to curb the self-referral temptation. "Therefore, the preferred approach to address self-referral is to develop payment systems that reward providers for constraining volume growth while improving the quality of care," states MedPAC's June 2010 report to Congress. "Integrated delivery systems that are able to coordinate care and manage resource use are likely to perform better under such a payment model than unaffiliated individual providers."

Three other approaches Goldsmith and Hillman advocate in their book are paying physicians more for their cognitive work, tort reform, and rethinking prior authorization. "We advocated giving physicians who are willing to install intelligent physician-order entry systems that incorporate appropriateness criteria a pass for review by the radiology benefit management companies — and they could potentially be paid more for the studies they do because they have absorbed some of the financial as well administrative responsibility for managing those appropriateness concerns directly," Goldsmith says.

Of course, stricter regulations could curb self-referral as well. "If I were a commercial insurer, I would strongly support legislation that limits the kind of ownership that physicians can have," Gabel says. Mitchell advises more draconian measures. "Private payers could just stop paying for it, but they are more afraid of pushback from providers," she says. "The providers really bully the insurers."

She has also advocated Medicare adopting get-tough measures. "My thoughts are if you took 10 doctors in each state and went after them, kicked them out of Medicare, you'd see all this stop," she says. At the same time, she acknowledges, "Self-referral is a political hot potato."

But Mitchell sees no other way. "Until somebody gets caught and put in jail or fined dramatically, they will continue to do it."

Richard Mark Kirkner is a health care journalist residing in Phoenixville, Pa. Reach him at RKirkner@ManagedCareMag.com.

Surgeries increased more rapidly among owners of ASCs

"than their counterparts who didn't have ownership status," says John Hollingsworth, MD, a University of Michigan urologist and economist.

A commercial insurer would want to be assured of good utilization management, says Jon Gabel, PhD, of National Opinion Research.

More like this

- Self-Referral Persists Despite Stark II Law
- Quick results, not self-referrals, fuel increase in imaging tests
- High-Tech Imaging Used Increasingly
- New Imaging Controls Strict, But May Be Easier on Doctors
- OIG Approves 'Safe Harbors' For Ambulatory Surgery Centers

PTCommunity News Headlines

Prostate Cancer Survival Improves With Earlier Use of Docetaxel

Simultaneous use of chemotherapy and a hormone blocker benefits patients in trial

Medicare Rule May Needlessly Extend Some Hospital Stays

Minimum-stay requirement dates to 1960s

New Diagnostic Guidelines for Myeloma

Experts revise international staging system

Ovarian Cancer Survival Is Higher Than Widely Believed

California study finds about one in three patients are alive after 10 years

Pfizer and Synthon Join for Potential Generic Treatment of Multiple

8/6/2015

The Enduring Temptation of Physician Self-Referral | Managed Care Magazine Online

Sclerosis

Generic version of Copaxone currently under FDA review

EXHIBIT 5



Med Care. 2009 April; 47(4): 403-410.

Published in final edited form as:

Physician ownership of ambulatory surgery centers and practice patterns for urological surgery: Evidence from the State of Florida

Seth A. Strope, MD, MPH, Stephanie Daignault, MS, John M. Hollingsworth, MD, MS, Zaujun Ze, MS, John T. Wei, MD, MS, and Brent K. Hollenbeck, MD, MS
Department of Urology, Division of Health Services Research University of Michigan Health System 1500 East Medical Center Drive TC 3875-0330 Ann Arbor, MI 48104

Abstract

Objective—To evaluate the relationship between ownership and use of ambulatory surgical centers (ASCs).

Methods—From 1998 through 2002, ambulatory surgical discharges for procedures within the genitourinary system were abstracted from the Florida State Ambulatory Surgery Database. State-wide utilization rates for ambulatory surgery were calculated by physician-level ownership (using an empirically-derived, externally-validated method) and financial incentives. A surgeon level Poisson regression model was fit to compare the rates of surgery by year, ownership, and their interaction.

Results—Rates of ambulatory surgery increased from 607 per 100,000 in 1998 to 702 per 100,000 in 2002 (p < 0.01 for trend). While rates at the hospital increased only slightly (0.9%), those at the ASC were up by 53% (p < 0.01). Physician ownership was associated with this greater utilization as new owners increased their use from 9 per 100,000 to 94 per 100,000 (p < 0.01) in the first full year as owners. In the first year of ownership, the proportion of a new owner's surgeries comprised of financially lucrative procedures increased to 61% compared to 50% in the year preceding ownership (p < 0.01).

Conclusions—Physician ownership is associated with the increasing use of ASCs, although the extent to which this is attributable to previously unmet demand is unclear. However, new owners appear to alter their procedure-mix after establishing ownership to include a greater share of financially lucrative procedures.

Keywords

Access/demand/utilization; ambulatory/outpatient; surgery; health care costs; incentives in health care

INTRODUCTION

With quality deficits pervasive ¹⁻³ and expenditures skyrocketing,^{4, 5} pressures to provide better and more proficient care continue to shape the landscape of the U.S. health care system. Payers, both federal and private, have laid out several initiatives designed to curtail costs, including value-based reimbursement programs,^{6, 7} cost-shifting expenses to the consumer,⁸ reducing reimbursements for physicians,⁹ and steering health care to more efficient settings.

Indeed, shifting certain surgical services to the ambulatory surgical center (ASC) appears to represent a convergence of cost reduction and quality improvement initiatives. ^{11, 12} Some specialized surgical facilities deliver better quality with lower overall cost. ^{10, 13} For example,

Strope et al.

the Shouldice clinic in Ontario Canada has been subject to multiple Harvard Business School case studies because of its focused model of care delivery, which is associated with lower overall health care costs.

However, the promise of better and more efficient health care at the ASC will only be fully realized if their use is immune from perverse financial incentives. Most freestanding ASCs are physician owned, ¹⁴ and are essentially impervious to self-referral regulations. ¹⁵ In the current climate of declining professional reimbursement, ¹⁶ some physicians have sought to replace lost revenue with alternative income sources, including investing in facilities such as ASCs. ¹⁷ Such ownership interests provide a mechanism for surgeons to increase their revenue stream while performing the same amount of billable services. With a facility ownership interest, some physicians may lower thresholds for treatment thereby increasing the utilization of surgery within a population. ¹⁸ In this context, the potential benefits realized by improved efficiency may be limited or even eliminated.

The structure of health care reimbursement in the United States incentivizes physicians for providing "more" care. ¹⁹ This perverse incentivization may be further compounded by facility ownership and the specter of physician-induced demand. However, surgeons can only take advantage of these added incentives by investing in ASCs. For this reason, we examined population-based rates of ambulatory surgery, and explored their associations with an empirically derived measure of physician ownership of these facilities. We sought to test the hypothesis that growth in ASC use, for better or worse, is related to new surgeon investment in ASCs, and to evaluate the effect of establishing ownership on practice patterns.

METHODS

Study Population

We first identified all patients in the Florida State Ambulatory Surgery Database (SASD) who underwent ambulatory surgery between 1998 and 2002. The SASD is a compendium of datasets from 24 state Data Organizations administered by the Federal Agency for Healthcare Research and Quality as part of the Healthcare Cost and Utilization Project. These data provide patient level discharge data for 100% of the ambulatory patients from facilities in the participating states. Plorida was chosen as a substrate for this study because the state tracks discharges from freestanding ASC in addition to hospital outpatient departments. Further, Florida accounts for the largest number of discharges of any state, ranging from over 2.5 million individual records in 1998 to 3.0 million in 2002. Also, Florida does not subject medical facilities to certificate of need requirements, allowing physicians and investors to respond to changing market demands for health care.

We limited our population to those undergoing procedures of the male genitourinary system and female urinary system as dictated by current procedure terminology (CPT) codes. These procedures are typically performed by urologists, a single specialty, thereby reducing potential bias due to cross specialty competition. CPT codes performed on fewer than 30 occasions annually or those only in the hospital setting were excluded. After these exclusions, we used 87 procedures for the analysis, as shown in Appendix 1.

Identifying Physician Owners

Similar to specialty hospitals, ²² ASCs are typically physician-owned. ¹⁴ Consequently, it is plausible that physician-owners would be more likely to perform a greater share of their ambulatory surgery caseload at these facilities than would the non-owners. This assumption has face validity and is supported by similar relationships for specialty hospitals, ²² and current Medicare safe harbor requirements for physician ownership. ¹⁴

Medicare safe harbor requirements guide the financial relationships between physicians and those facilities in which they have invested. There are four categories of such relationships that were established, including surgeon-owned ASCs, single specialty ASCs, multispecialty ASCs, and hospital/physician-owned ASCs. ²³ In all four arrangements, the physician-owner is required to obtain one-third of his practice income from procedures that can be performed in an ASC or hospital setting. Additionally for multispecialty facilities, owners must perform at least one third of their procedures in the facility in which they have invested. ²³

Because the ASCs within this study population were multispecialty, we chose to define physician-owners as those surgeons who performed more than 30% of their ambulatory surgery cases within a single ASC in each year. Surgeons were followed over the five years of the study through the use of a surgeon identifier available in the SASD. Because ownership is empirically derived, it was possible for surgeons to change their status yearly within the data. Those who did not change their status were considered 'always owners' (n = 111, 13%) or 'always non-owners' (n = 600, 70%). A smaller number of surgeons switched a single time, either from owners to non-owners ('new non-owners', n = 37, 4%) or vice versa ('new owners', n = 75, 9%). Surgeons who changed their status more than once over the five years of the study (n = 39, 4%) were analyzed both as a unique group and with the 'always non-owners'. Because analyzing this group of surgeons as a separate group did not lend any additional information or change any of the findings, they were aggregated with the 'always non-owners' in the final analysis.

External Validation of Ownership Definition—To provide validation for our empiric definition of ownership, we examined the actual ownership records of ASCs through publicly available records from the Florida Department of State Division of Corporations. ²⁴ Due to data use limitations with the State Ambulatory Surgery Database, we could not directly identify individual surgeons in the SASD dataset, or link the surgeons and facilities between the two data sources. Rather we determined the ownership of ASCs using publicly available incorporation records from the Florida Department of State, and used the Florida Department of Health physician locator function to determine the specialty of the physician-owners within these documents. For owners who were urologists, the physician locator was then used to find the physicians who practiced at the same address as the index owner. The total number of physician-owners in the facility was then determined, and compared to the number derived from our empirical definition.

From the Florida Health Stat website, we found 60 facilities that performed 10 or more urologic procedures in 2004. We were able to determine the ownership status of 51 of the facilities; 49 for-profit and 2 not-for-profit. In the SASD data, we then examined the number of surgeons in each facility for which ownership could be determined. In the not-for profit facilities, 19 of 21 surgeons who operated in the facilities were properly classified as non-owners. Of the 49 for-profit facilities, ownership was traced back owners with specialties listed as urology in 17 facilities. In these 17 facilities, we identified 88 actual physician-owners compared to 93 using our empirically based criteria.

Defining Financial Incentives

All physicians regardless of their ownership status collect the same fee for professional services from third party payers. These professional fees are used by payers to encourage the performance of procedures in locations advantageous to the payer. To obtain a marker of the location of care encouraged by payers, we used the Medicare reimbursement for each procedure from the American Medical Association's online CPT finder. ²⁶ If a procedure was reimbursed at a higher rate in an office setting than in a hospital or ASC, the procedure was considered to have an incentive for the office.

Although the financial incentives for non-owners are straightforward, for owners they become much more complex. Owners share in some or all of the facility fees generated by the surgery center in which they have invested. Thus the revenue stream for procedures performed in an ASC by a physician-owner is a combination of the facility and professional fees. Costs are associated with the provision of care in the ASC, however for similar procedures; similar costs apply to the provision of care in the office. Thus the total revenue generated by physician-owners when performing procedures in owned ASCs is very different from non-owners.

To gauge this differential, we examined the 2006 Medicare reimbursement to ASCs from the Federal Register.²⁵ For each procedure, the facility fee was added to the professional fee to obtain the maximum revenue available to a physician-owner. This maximum revenue was then subtracted from the office reimbursement. If this resulting figure was positive, the physician-owner had a financial incentive to perform the procedure in the office. If this figure was negative, the physician-owner had a financial incentive to perform the procedure in the ASC.

A case study for a single code in the study, 52000 (cystoscopy), clarifies the impact of the differences between owners and non-owners. When this procedure is performed in an office, the Medicare reimbursement is approximately \$200 (USD). Performance of this procedure in the ASC results in a professional fee of approximately \$100. When performed in an ASC, a physician-owner would recoup approximately \$440 (USD), \$100 (USD) from the professional fee and \$340 (USD) from the facility fee. Thus, the non-owner would have an incentive for office practice (office — facility = +), while the owner would have an incentive for the ASC [office — (facility + ASC) = -].

Payers use the professional and facility fees to encourage the migration of care to the most efficient setting. For most procedures where the office and facility professional fees are equal, payers have no preferred location of care. By default the location of care is a facility (hospital or ASC) because of the lack of reimbursement for overhead if the procedures are performed in an office. For those procedures where payers provide higher professional fees for office care, the preferred location of care from a payer's perspective would be the office. We thus examined the differences in incentives set by payers for office practice to the incentives created by ownership in ASC.

When the incentive for ASC use was present, and the incentive for office based practice was neutral, the use of the ASC was aligned with payer's interest for efficiency. If the incentive for ASC use was present, and the incentive for office was positive, the procedure was considered misaligned from the payer's perspective. Returning to the example of CPT code 52000, since physician-owners have an incentive to perform the procedure in an ASC, and the payer encourages performance in the office, this code represents a case of a misaligned incentive for physician-owners. We have included in Appendix 1 all of the office incentive values, ASC incentive values for owners, and the incentive category for owners and non-owners.

Utilization of the ASC

Our primary outcome measure was the rate of ambulatory genitourinary surgery. The rates were standardized to the U.S. Census Bureau's population estimates for the State of Florida in each of the studied years, and were stratified by setting (hospital vs. ASC), ownership status, and incentive status. Using linear and Poisson regression respectively, the rate of utilization within categories of ownership and incentive status were assessed. Comparisons between ownership categories, financial incentives, and locations of practice were based on interaction terms involving time to assess changes over time.

With overall utilization and stratified rates determined, a surgeon-level Poisson model was fit to assess the relationship between ownership, incentives, and rates. The Poisson model was

used to account for the dependent variable being counts of procedures transformed to rates. For this purpose, surgeons with more than 30 total cases for the five years of our study were included. The surgeon level utilization rate was determined by calculating the count of procedures by the surgeon divided by the population in the state of Florida for that year. We used generalized estimating equations to account for the repeated measures design of the model. The model took the following form:

count=Ln λ + β_0 + β_1 Year+ β_2 Ownership Class+ β_3 (Year × Ownership Class)

Ln λ is the log offset in the Poisson model. Year was treated as a continuous variable with 1998 serving as the reference. Ownership class was a categorical variable with the always non-owners serving as the reference group. An interaction term was included to test the trend of utilization by owner group over time.

Finally, we examined the procedure mix (e.g., the types of ambulatory surgery) according to financial incentives at both the hospital and ASC among new owners. All surgeries in the year prior to ownership and those in the year after were examined. The change in procedure-mix (in terms of place of practice) was then assessed via a chi-square test. Using the Medicare reimbursement for procedures, we estimated the cost to payers of performing misaligned cases in the ASC instead of the office in the year prior to and after ownership changes among the new owners.

All testing was conducted using SAS Version 9.1.2 (SAS Institute, Cary, NC) using two-sided tests. The probability of Type 1 error was set at 0.05. This study, dealing with publicly available data was exempt from institutional review board approval in accordance with the Code of Federal Regulations, Title 45, Section 46.101.

RESULTS

There were 805,400 total discharges between 1998 and 2002 for procedures of the male genitourinary system and female urinary system. After excluding procedures performed fewer than 30 times per year or performed only in the hospital setting, the final cohort included 543,031 discharges for analysis. There were 335 unique facilities in the data, 203 hospitals and 103 ASCs. The number of surgeons and facilities by year are displayed in Figure 1.

Overall, we observed an increase in ambulatory genitourinary surgery use from 607 per 100,000 Florida residents in 1998 to 702 per 100,000 Florida residents in 2002, an increase of 16%. The bulk of this increase was driven by greater use of the ASC. During the study period, ambulatory procedures performed at ASCs increased by 53% compared to only 0.9% at hospitals (Figure 1) (p < 0.0001 for difference in rates). Further, we see that the majority of procedures in the hospital were performed by always non-owners while the bulk of those in the ASC were performed by always owners. Both groups of surgeons with stable ownership status throughout the study period had stable rates of ambulatory surgery. The rates of ambulatory surgery performed by the always non-owners increased from 348 per 100,000 in 1998 to 381 per 100,000 in 2002 (p-value = 0.6379). A similar small increase in the rates was observed for the always owners (152 per 100,000 in 1998 to 158 per 100,000 in 2002, p-value = 0.6975).

While the financial reimbursements for these procedures remained stable between 1998 and 2002, surgeon practice patterns changed dramatically during the same period. Overall, the provision of ambulatory surgery by new owners increased from 73 per 100,000 in 1998 to 129 per 100,000 in 2002 (p=0.002). New-owners decreased their use of the hospital (from 65 per 100,000 in 1998 to 35 per 100,000 in 2002, p < 0.0001), but increased their use of the ASC by

10-fold (9 per 100,000 in 1998 to 94 per 100,000 in 2002, p < 0.0001). New non-owners maintained stable rates of ambulatory surgery (29 per 100,000 in 1998 to 29 per 100,000 in 2002, p = 0.9310), but moved their location of service from the ASC into the hospital.

When classified by incentive status (Figure 2), the rates of surgery within the hospital by ownership status were stable. However, the use of ASCs by owners for procedures with misaligned incentives increased from 100 per 100,000 to 168 per 100,000 (p < 0.0001). Overall, the proportion of cases with misaligned incentives in the ASC increased from 58% in 1998 to 64% in 2002.

When modeled at the surgeon level, new owners were significantly more likely to use the hospital and ASC than the always non-owners at baseline in 1998 (chi-square p < 0.0001 for hospital and p = 0.0043 for ASC). The always owners and the new non-owners also showed a significantly increased use of the ASC at baseline compared to the always non-owners (chi-square p < 0.0001 for both). However, with the interaction term added to the model, no significant differences were found in the use of the hospital between the different types of surgeons (Table 1). In the ASC, only the new owners showed significant increases in use over time (chi-square p < 0.0001). To assess the robustness of the measure of ownership, we reexamined the model after limiting the data set to physicians who performed procedures in facilities where ownership was tracked. Both new owners and always owners had significant decreases in their rates of hospital use over time (Chi Square p < 0.0001). As in the model using all physicians, new owners had increased ASC use compared to always non-owners, although the increase fell just short of statistical significance (Chi Square p = 0.0576).

The distribution of procedures for the new owners was then examined for the years before and after establishing ownership (Figure 3). The distribution of where cases were performed changed significantly (Chi-Square; p < 0.0001). For the new owners, the procedures with misaligned incentives increased from 50% to 61% of all their cases in the year before and after ownership, respectively. If cases with misaligned incentives performed in the ASC were instead done in the office (i.e., the preferred setting from a payer perspective), the cost savings would be \$108,074 and \$590,243 for the years preceding and following ownership change, respectively.

DISCUSSION

In this study, we demonstrate that rates of genitourinary ambulatory surgery are associated with an empirically derived measure of physician ownership of the ASC. Although ASCs were conceived as facilities where all surgeons would perform procedures, non-owners rarely used these facilities. Further, the use of hospitals for ambulatory procedures has remained stable over the study period, while rates of procedures in ASC have increased sharply. This increase was associated with the conversion of non-owners to owners, and a behavioral shift among these new owners to emphasize the performance of procedures with misaligned financial incentives in their procedure mix after establishing ownership.

Overall, our results raise concerns about the ability of the physician-owned ASC to reduce overall health care costs. Medicare reimbursement policies were changed in the early 1990s to favor office based practice as a cost control measure, ²⁷ with private insurers soon following. ²⁸ An inherent problem with these measures is the inconsistency of the physician response. ²⁹ Some physicians respond by decreasing the performance of the procedure with decreasing reimbursement and substituting new procedures. ¹⁸ Others increased procedural volume to compensate for situations where the reimbursement was reduced in order to maintain a targeted income. ³⁰ This demand induction has been a major concern of policy makers when they impose fee reductions. ³¹

While one cannot conclude that the physicians in this study are inducing demand, the phenomenal growth of ASC use for procedures intended to be performed in the office setting is certainly concerning. In fact, for non-owners, these procedures are among the most lucrative procedures available to urologists on an hourly rate basis. In this context, ASC use for these procedures could reflect movement of procedures out of the office (for example to meet safe harbor requirements for ownership status), or lowered thresholds for intervention among new owners. In either scenario, our findings would suggest that incentives designed to promote office-based procedures are being overwhelmed by the additional revenue generated as a result of ASC ownership, likely resulting in unnecessary costs to the US health care system. This added cost may represent value to the physician with higher reimbursement, possible value to the patient if the ASC is a better environment for surgery than the office, and decreased value for payers because they pay more for the same services.

Understandably, payers want to encourage the performance of surgery in the least costly and safest setting. In the desire to shift cases out of the hospital, they have set physician payments to encourage office-based practice. However, the incentives established to encourage office-based procedures clash with those fostering ASC promulgation, through the added remuneration of the facility fee by physician owners. These conflicting incentives likely contribute to physician investment in ASCs, and to the consolidation of surgical groups that then invest in single-specialty ASCs. 32

When these conflicts have occurred in the past, policy has been changed to discourage physician investment in ancillary services. Research on self referral for radiological procedures, ³³, ³⁴ physical therapy, ³⁵ and radiation oncology ³⁶ led to regulatory action to prevent abuses from ownership interests. ²³, ³⁷ Such regulatory action continued with the temporary moratorium on specialty hospital creation, which was released in 2005. ³⁸ The use of such hospitals has been associated with increased use of coronary revascularization, ³⁹ but not increased quality of care. ⁴⁰ Our findings support these previous studies, and lend additional support to the contention that physician incentives need to be carefully considered when implementing reimbursement policy.

Instead of allowing physician ownership of ASCs, state or federal regulations could prohibit such ownership, or prohibit new investments in such physician-owned facilities (as has occurred for specialty hospitals). In this counterfactual situation, current non-owners would not be able to become owners. Thus, this group of surgeons would not be able to respond to the financial incentives associated with facility ownership. They would likely continue a stable practice style, and not demonstrate the changes in the distribution of cases among facilities we observed for the new owners. Alternatively, total reimbursement (physician and facility) for a procedure could be capped at the equivalent of the office-based professional fee. In this case, the misaligned incentives would be removed.

Our findings should be interpreted with several caveats in mind. First, ownership was defined based on the percentage of a surgeon's case done in a single ASC. This empirically-derived measure was created because no direct listing of physician ownership interest of ASCs is available. Our definition threshold of 30% of cases in a single ASC is consistent with Federal rulings on safe harbors for both anti-kickback statutes and Stark laws. Though this definition may have classified some non-owners as owners, the data support a significant change in physician behavior after they become owners (Figure 3). Thus, it seems unlikely that the significant increase in ASC use we find among the new owners is a result of misclassification of non-owners into the ownership category due to fluctuation around the 30% threshold. Furthermore, our validation study for the ownership definition allays some of the concerns about using an empiric measure, and the results were robust to limiting the data set to physicians who practiced within ASC where ownership could be confirmed. Finally, endogeneity of the

ownership definition and the outcome variable could be a concern. To alleviate this concern, the dependent variable in the regression was the count of procedures at the surgeon level, and the definition of ownership based on the percentage of procedures performed in the ASC was independent of the outcome variable. An individual surgeon could have a rising count of procedures without a change in ownership status, or conversely could have a change in ownership status without any change in the number of procedures performed.

Second, while it would have been ideal to observe concurrent changes in office-based procedures, these are not tracked within the SASD dataset. Since the majority of the procedures performed by these new owners come from procedures with misaligned incentives, it is probable that they represent office-based procedures that have been moved into the ASC setting; however, this hypothesis cannot be further tested using the current data. As with similar studies, it is impossible to determine the 'right' rates of utilization for these procedures, many of which are preference-sensitive. It is possible that the observed rates may reflect previously unmet demand or patient preference for a particular setting of care.

Third, we chose to examine data from Florida, a state that may not be representative of the country as a whole. Florida has a more elderly population than many other states, more for profit facility ownership, and higher per capita health care use than other states. Despite these issues, Florida provides a valuable substrate for this study because of the lack of certificate of need legislation, the ability to track surgeons in the data, the inclusion of freestanding ASC in the data, and the diverse population in the state. Due to these factors, the results of this study can be generalized to other areas where physicians are able to make new investments in ASCs.

Conclusions

New physician investment in ASCs in the context of the current reimbursement structure is concerning. Procedures performed by the new owners of these facilities are likely those that are performed by non-owners in their office. Since physician-owners of ASCs generate more revenue through the use of these facilities, they have direct financial incentives to increase the delivery of care, and to move procedures from the less costly office setting to the ASC. Such movement will invariably lead to increased costs to the US health care system. Changes to health care policy that properly align financial incentives of physicians with the interests of patients and payers will ultimately limit the negative effects of ASC development while continuing to provide a necessary alternative to the hospital outpatient department.

Appendix

Appendix 1: Codes and Incentives

Office incentive is derived by subtracting the professional fee for performance of the procedure in a facility (ASC or hospital) from the professional fee for performing the procedure in the office.

ASC incentive is derived by subtracting the combined facility fee for the ASC and professional fee for performance of the procedure in the facility from the professional fee for performance of the procedure in the office.

The numbers for the incentives represent the following types of incentives:

0 = non-owner office incentive

I = non-owner no incentive

2 =owner office incentive

3 = owner ASC incentive (aligned)

4 = owner ASC incentive (misaligned)

5 = owner no incentive

REFERENCES

- Asch SM, Kerr EA, Keesey J, et al. Who is at greatest risk for receiving poor-quality health care? N Engl J Med Mar 16;2006 354(11):1147–1156. [PubMed: 16540615]
- Birkmeyer NJ, Birkmeyer JD. Strategies for improving surgical quality--should payers reward excellence or effort? N Engl J Med Feb 23;2006 354(8):864-870. [PubMed: 16495401]
- Pogach L, Engelgau M, Aron D. Measuring progress toward achieving hemoglobin A1c goals in diabetes care: pass/fail or partial credit. Jama Feb 7;2007 297(5):520-523. [PubMed: 17284702]
- Banthin JS, Bernard DM. Changes in financial burdens for health care: national estimates for the population younger than 65 years, 1996 to 2003. Jama Dec 13;2006 296(22):2712–2719. [PubMed: 17164457]
- Cutler DM, Rosen AB, Vijan S. The value of medical spending in the United States, 1960-2000. N Engl J Med Aug 31;2006 355(9):920–927. [PubMed: 16943404]
- Rosenthal MB, Landon BE, Normand SL, Frank RG, Epstein AM. Pay for performance in commercial HMOs. N Engl J Med Nov 2;2006 355(18):1895–1902. [PubMed: 17079763]
- Milgate K, Cheng SB. Pay-for-performance: the MedPAC perspective. Health Aff (Millwood) Mar-Apr;2006 25(2):413–419. [PubMed: 16522581]
- 8. Johnson TJ, Rimsza M, Johnson WG. The effects of cost-shifting in the state children's heath insurance program. Am J Public Health Apr;2006 96(4):709–715. [PubMed: 16507728]
- Lotan Y, Cadeddu J, Roehrborn C, Stage K. The value of your time: evaluation of effects of changes in medicare reimbursement rates on the practice of urology. Journal of Urology 2004;172(5):1958– 1962. [PubMed: 15540765]
- Casalino LP, Devers KJ, Brewster LR. Focused Factories? Physician-Owned Specialty Facilities. Health Aff November 1;2003 22(6):56–67.2003
- Kamil J. Are cost controls bad medicine? NO: Managing resources can save more lives. San Francisco Chronicle June 29;2006 B:11.
- 12. CMS. Medicare program; hospital outpatient prospective payment system and CY 2007 payment rates; CY 2007 update to the ambulatory surgical center covered procedures list; Medicare administrative contractors; and reporting hospital quality data for FY 2008 inpatient prospective payment system annual payment update program--HCAHPS survey, SCIP, and mortality. Final rule with comment period and final rule. Fed Regist Nov 24;2006 71(226):67959–68401. [PubMed: 17133695]
- Herzlinger RE. Specialization and Its Discontents: The Pernicious Impact of Regulations Against Specialization and Physician Ownership on the US Healthcare System. Circulation May 25;2004 109 (20):2376–2378. [PubMed: 15159326]2004
- 14. Becker S, Biala M. Ambulatory surgery centers--current business and legal issues. Journal of Health Care Finance Winter;2000 27(2):1–7.
- Zientek DM. Physician Entrepreneurs, Self-Referral, and Conflicts of Interest: An Overview. HEC Forum 2003;V15(2):111–133. [PubMed: 12918281]
- 16. CMS. Medicare program; revisions to payment policies, five-year review of work relative value units, changes to the practice expense methodology under the physician fee schedule, and other changes to payment under part B; revisions to the payment policies of ambulance services under the fee schedule for ambulance services; and ambulance inflation factor update for CY 2007. Final rule with comment period. Fed Regist Dec 1;2006 71(231):69623–70251. [PubMed: 17171850]
- O'Leary, Baum, Bohnert, et al. 2003 American wrological association Gallup survey: Physician practice patterns, cryosurgery/brachytherapy, male infertility, female urology and insurance/ professional liability. The Journal of Urology 2004;171(6):2363–2365. [PubMed: 15126822]

 Hadley J, Reschovsky JD. Medicare fees and physicians' medicare service volume: Beneficiaries treated and services per beneficiary. International Journal of Health Care Finance and Economics 2006;V6(2):131–150. [PubMed: 16783506]

- Fisher ES. Medical Care -- Is More Always Better? N Engl J Med October 23;2003 349(17):1665– 1667. [PubMed: 14573739]2003
- 20. AHRQ. Introduction to the HCUP State Ambulatory Surgery Database (SASD). 13 062007 [Accessed August 29]. http://www.hcup-us.ahrq.gov/db/state/sasddist/Introduction_to_SASD.pdf
- 21. AHCA. State of Florida Agency for Health Care Administration Office of Plans and Construction: Information for Project Review. [Accessed August 28]. http://www.fdhc.state.fl.us/MCHQ/Plans/pdfs/Information_for_Project_Review_Packet.pdf [http://www.fdhc.state.fl.us/MCHQ/Plans/pdfs/Information_for_Project_Review_Packet.pdf
- Mitchell JM. Effects Of Physician-Owned Limited-Service Hospitals: Evidence From Arizona. Health Aff. October 25;2005 2005:hlthaff.w5.481
- OIG. Medicare and state health care programs: fraud and abuse; clarification of the initial OIG safe harbor provisions and establishment of additional safe harbor provisions under the anti-kickback statute. Office of Inspector General (OIG), HHS. Final rule. Fed Regist Nov 19;1999 64(223):63518– 63557. [PubMed: 11010662]
- 24. Florida. Document Searches. [Accessed September 4]. http://www.sunbiz.org/
- CMS. Medicare program; update of ambulatory surgical center list of covered procedures. Interim final rule with comment period. Fed Regist May 4;2005 70(85):23689–23768. [PubMed: 15871172]
- AMA. CPT Online, [Accessed January 12]. https://catalog.ama-assn.org/Catalog/cpt/cpt_search.jsp?checkXwho=done
- Mitchell JB, Cromwell J. Impact of Medicare payment reductions on access to surgical services. Health Serv Res Dec; 1995 30(5):637–655. [PubMed: 8537224]
- 28. Committee on Coding and N. Application of the Resource-Based Relative Value Scale System to Pediatrics. Pediatrics May 1;2004 113(5):1437–1440. [PubMed: 15121969]2004
- Mitchell JMHJ, Gaskin DJ. Physicians' responses to Medicare fee schedule reductions. Med Care 2000;38(10):1029–1039. [PubMed: 11021676]
- Yip WC. Physician response to Medicare fee reductions: changes in the volume of coronary artery bypass graft (CABG) surgeries in the Medicare and private sectors. Journal of Health Economics 1998;17(6):675–699. [PubMed: 10339248]
- 31. Zuckerman S, Norton S, Virilli D. Price controls and Medicare spending: Assessing the volume offset assumption. Medical Care Research and Review 1998;55(4):457–478. [PubMed: 9844351]
- 32. Hobbs B. Urology group takes different route. Nashville Business Journal. January 9;1998
- 33. Kouri BE, Parsons RG, Alpert HR. Physician self-referral for diagnostic imaging: review of the empiric literature. AJR Am J Roentgenol Oct;2002 179(4):843–850. [PubMed: 12239022]
- 34. Hillman BJ, Olson GT, Griffith PE, et al. Physicians' utilization and charges for outpatient diagnostic imaging in a Medicare population. Jama Oct 21;1992 268(15):2050–2054. [PubMed: 1404741]
- 35. Mitchell JM, Scott E. Physician ownership of physical therapy services. Effects on charges, utilization, profits, and service characteristics. Jama Oct 21;1992 268(15):2055–2059. [PubMed: 1404742]
- Mitchell JM, Sunshine JH. Consequences of physicians' ownership of health care facilities--joint ventures in radiation therapy. N Engl J Med Nov 19;1992 327(21):1497–1501. [PubMed: 1406881]
- 37. Medicare and Medicaid programs; physicians' referrals to health care entities with which they have financial relationships. Health Care Financing Administration (HCFA), HHS. Final rule with comment period. Fed Regist Jan 4;2001 66(3):856–965. [PubMed: 11503745]
- Final report to Congress implementing the DRA provision affecting specialty hospitals. http://www.cms.hhs.gov/apps/media/press/release.asp?counter=1941
- Nallamothu BK, Rogers MA, Chernew ME, Krumholz HM, Eagle KA, Birkmeyer JD. Opening of specialty cardiac hospitals and use of coronary revascularization in medicare beneficiaries. Jama Mar 7;2007 297(9):962–968. [PubMed: 17341710]
- 40. Nallamothu BK, Wang Y, Cram P, et al. Acute myocardial infarction and congestive heart failure outcomes at specialty cardiac hospitals. Circulation Nov 13;2007 116(20):2280–2287. [PubMed: 17967975]

Strope et al.

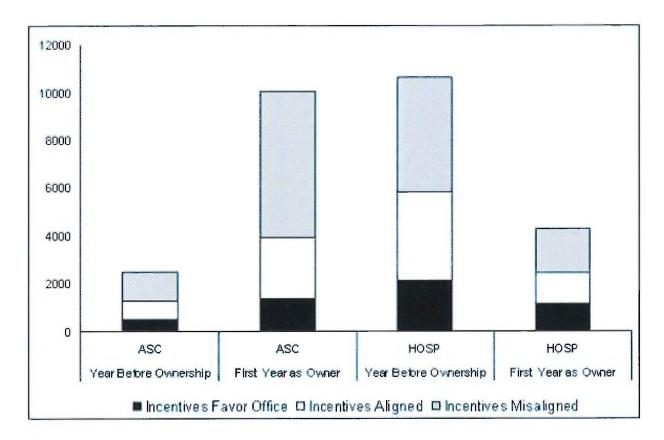


Figure 1. ASC and Hospital Outpatient Department Utilization by Year and Ownership Status ASC utilization increased from 171 per 100,000 to 262 per 100,000. Hospital utilization increased from 433 per 100,000 to 437 per 100,000. In the hospital, 'new owners' decreased their use of the outpatient department (65 per 100,000 to 35 per 100,000). The 'new owners' increased their ASC use (9 per 100,000 to 94 per 100,000).

The number of facilities, and the number of surgeons by each ownership category is given for each year.

NIH-PA Author Manuscript

NIH-PA Author Manuscript

NIH-PA Author Manuscript

Table 1
Hospital Outpatient Department and ASC Utilization by Year and Ownership Status

Hospital	Type of Owner	Rate of Sur	Rate of Surgery per 100,000 Florida Population	,000 Florida	Population	
		8661	6661	2000	2001	2002
3000	New Owner	65	58	8+	41	35
	Always Owner	31	34	35	30	29
	New Non- Owner	13	22	23	23	25
	Always Non- Owner	324	361	366	346	348
	Total Use	433	475	472	440	437
ASC						
	New Owner	6	30	52	71	94
	Always Owner	121	131	129	131	130
	New Non- Owner	17	∞	6	S	4
	Always Non- Owner	24	42	43	33	33
	Total Use	171	211	233	243	261

Strope et al.

Use Stratified by Incentives

D	1	-1
Page	- 1	4

Hospital	Incentive	Rate of Sun	rgery per 100	Rate of Surgery per 100,000 Florida Population	Population	
		8661	6661	2000	2001	2002
	Owner, Misaligned	61	29	25	29	31
	Owner, Aligned	18	26	27	21	22
	Owner, Office	12	17	18	61	20
	Non-Owner, No Incentive	171	172	173	145	139
	Non-Owner, Office	213	231	229	226	225
	Total Use	433	475	472	24	437
ASC						
	Owner, Misaligned	100	121	137	146	167
	Owner, Aligned	35	43	48	47	45
	Owner, Office	6	16	19	21	24
	Non-Owner, No Incentive	Ξ	6	10	6	10
	Non-Owner, Office	16	22	19	20	15
	Total Use	171	211	233	243	261

Page 14

NIH-PA Author Manuscri	Religion NIH-PA Author Manuscript	NIH-PA Author Manuscript	NIH-PA A
Estimates of the Year by Ownership Interaction Term	iteraction Term		
β3 Year × Ownership Class	Lower 95% ip Confidence Interval	5% Upper 95% Confidence Interval	Strope et a
0			
-0.0075	-0.0243	0.0093	0.3837
0.0007	-0.0121	0.0135	0.9107
0.0019	-0.0298	0.0336	0.9061
0			
0.0230	-0.0042	0.0502	0.0981
0.1211	0.0736	0.1686	<0.0001
-0.0799	-01894	0.0297	0.1530